ASIA NOW: Navigating the ASEAN Region

Medical Equipment & Supplies

INDONESIA

Market Overview

- Forecasted growth rate of 10%
- Over 85% of medical equip. and supplies are imported
- U.S. import market share was 17% in 2005

Best Prospects

- Electro-medical and diagnostic equipment
- Respiratory appliances
- X-ray units & film

PHILIPPINES

Market Overview

- Forecasted growth rate of 5% till 2008
- Imports account for nearly 100% of demand – US$101 million
- U.S. exports lead with a 24% market share in 2004

Best Prospects

- Ozone/oxygen therapy
- Artificial respiration devices
- Breathing appliances
- Ultrasonic scanners

THAILAND

Market Overview

- Forecasted growth rate of 15% over 2005-2006
- Imports account for 65 % of demand and totaled US$260 million in 2004
- U.S. leads the import market with a 32% share in 2004

Best Prospects

- Heart valves & artificial blood vessels
- Implant devices
- Quick diagnostic testing devices

MALAYSIA

Market Overview

- Forecasted growth rate of 8-10%
- 90% of medical equip. & supplies are imported
- U.S. import market share was 17% of total 2005 imports

Best Prospects

- Electro-medical app.
- Orthopedic appliances
- Diagnostic & therapeutic radiation devices

SINGAPORE

Market Overview

- Forecasted growth rate of 5-7%
- Over 85% of medical equip. & supplies are imported
- U.S. import market share was 23% of total imports

Best Prospects

- Health screening/diagnostics
- Disease management

VIETNAM

Market Overview

- Forecasted growth rate of 10%
- 90% of medical equip. & supplies are imported
- U.S. import market share was 30% in 2005

Best Prospects

- Imaging diagnostic equip. (X-ray, ultrasounds)
- Laboratory Equip.

Pre-Market Approval Requirements

Most ASEAN nations require that imported medical products be registered through a duly appointed local agent or a distributor. Please view the below matrix for pre-market approval requirements for each ASEAN nation. The objective of this report is to assist the U.S. medical device industry in understanding the country's regulatory process in order to work more effectively in gaining the necessary approvals.

	Indonesia 	**Malaysia** 	**Philippines** 
Governing Body	Directorate General of Pharmacy & Medical Devices Services, Ministry of Health	Ministry of Health	Department of Health
Local Clinical Trial Required	Yes, for some high risk products (i.e. in-vitro diagnostics).	No, though legislation is currently in the works.	None. Acceptable int'l standards for machineries/ equipment are recognized in the Philippines.
FDA Certificate of Foreign Gov. Required	FDA (US), CE (EU), TPP (Canada), TGA (Australia)	FDA (US), CE (EU), TGA (Australia), TPP (Canada), MLHW (Japan)	None for equipment of U.S. origin. (Certificates are usually required for consumables.)
Number of days for registration (from submission of data)	The standard administrative time clock for the approval process is three months	Regulation is being drafted	No registration required for medical equipment/ instruments at this point. Importer-distributors must be licensed by the Dept of Health.
Classification system of Medical Devices	Products are classified into three categories, low, middle and high risk.	Regulation is being drafted but at this point all medical devices except radiation emitting devices are freely imported.	Freely importable, except for radiation emitting devices, which need pre-registration.
Requirement for Market Clearance	Products must comply with regulatory provisions in the country of origin and meet the quality, safety and performance standards. Registration must be done by local agent/distributor. The agent/distributor must obtain license to import and distribute products from Ministry of Health.	Voluntary registration is on-going before full enforcement by 2008	A distributor-representative of imported medical equipment must have a license to import such devices, and a license to operate as a distributor.
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Pre-Market Approval Requirements

	Singapore	Thailand	Vietnam
Governing Body	Ministry of Health, Health Sciences Authority's (HSA) Centre for Medical Device Regulation (CMDR)	Food and Drug Administration, Ministry of Public Health (MOPH)	Ministry of Health
Local Clinical Trial Required	No	No	No
FDA Certificate of Foreign Gov. Required	FDA (U.S.), TGA (Australia) CE (E.U.), MLHW (Japan), TPP (Canada)	Yes	Yes
Number of days for registration (from submission of data)	8-10 weeks for evaluation of abridged submissions (products with prior regulatory approval)	30	According to the law, 15 working days after completed application submission
Classification system of Medical Devices	Aligned to major regulatory efforts to ensure quality, safety and efficacy of medical devices. Product Notification is expected for low-risk Class I medical devices and general invitro devices (IVDs) and Product Registration for high-risk Class IIa, Iib and II medical devices and self-testing IVDs.	**3 Classes** Class 1- requires MOPH authorization – HIV Kits, Syringes Class 2 – requires a notification to MOPH – Rehab Equipment Class 3 – Other General Devices – Certificate to Foreign Government	None
Requirement for Market Clearance	Currently, medical devices aren't under statutory control, but manufacturers of medical devices must ensure that all devices placed on the market comply with regulatory provisions in their country of origin and meet essential requirements on safety, quality and performance. Statutory control is expected to take effect at the end of 2006.	None	Registration must be done by local agent/distributor. The agent/distributor must obtain a license to import products from the Ministry of Health.
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